MEDICAL INSTRUMENT

TECHNICAL FIELD

[0001] The present invention relates to a medical instrument (a catheter device) that cuts deposits from a narrowed coronary artery or other vascular site with a rotating cutter means to establish patency of a passageway through the vascular site or to distend the narrowed vessel.

BACKGROUND ART

[0002] To treat a disease caused by deposits on the wall of a blood vessel, it is customary to insert a catheter device into a patient's body down to an intravascular treatment site to remove the deposits or to distend the narrowed vessel.

[0003] Fig. 15 is a schematic diagram explanatory of a procedure for scraping deposits off the wall of a blood vessel.

[0004] The first thing to do is to insert a small-diameter guide wire 105 into a blood vessel 101 and navigate it past a narrowed vascular site 107, followed by inserting a small-diameter catheter device 125 into the vessel along the guide wire 105. The catheter device 125 has a shell-like grindstone 127 and a drive shaft 129 formed by a coiled wire. The next step is to drive the grindstone 127 of the catheter device 125 at high speed (approximately 200,000 rpm, for instance) to grind away deposits 103 to broaden first the entrance of the narrowed vascular site 107 up to a diameter of around 1 mm for ease in centering the grindstone 127, which is then inserted in its entirety through the narrowed vascular portion.

[0005] Following this, the catheter device 125 is pulled out of the vessel, with the guide wire 105 left remaining therein intact, and another catheter device with a slightly larger-diameter grindstone is inserted into the vessel along the guide wire and is driven to scrape the deposits 103 in the same manner as mentioned above. This operation is repeated using catheter devices that are replaced one after another in ascending order of grindstone diameter to gradually enlarge the diameter of the narrowed vascular site 107 up to an ultimate value of approximately 2.5 mm.

[0006] In this way, the catheter device has a rotary cutting bar (grindstone 127) held rotatable and slidable with respect to the guide wire 105 passing through the narrowed vascular site, and

drives the rotary cutting bar at high speed to thereby grind away calcified deposits on the wall of the narrowed blood vessel.

[0007] The above-mentioned conventional rotary cutting bar (a rotor ablator, the grindstone 127 in Fig. 15) has a rigid structure that has the bar surface formed by a grinding surface coated with abrasive grains, but has no vessel distending mechanism. On this account, in a case where it is desirable to distend a narrowed blood vessel to a diameter larger than that obtained by previous removal of calcified deposits, the rotary cutting bar (grindstone 127) needs to be completely pulled off from the guide wire (105), together with the drive shaft (129), and exchanged for a rotary cutting bar of a larger diameter. In nearly 40% of the past cases, two large- and small-diameter versions were used for each of the rotary cutting bar (grindstone 127) and the drive shaft (129) (an average number used per case being 1.4), and they needed complicated replacement work in a clean region in an operating room.

[0008] In this respect, since the conventional rotary cutting bar (a rotor ablator, a grindstone) is held unitary with the drive shaft, its replacement is required to follow the below-listed steps 1 to 7, and hence it is complicated.

[0009] The procedure for replacement comprises the steps of:

1. Disengaging the drive shaft (129 in Fig. 15) from a drive control assembly;
2. Pulling the drive control assembly off the guide wire;
3. Pulling the rotary cutting bar and the drive shaft (grindstone 127 and drive shaft 129) out of a patient's body in their entirety and then pulling them off the guide wire, too;
4. Putting a rotary cutting bar and a drive shaft (grindstone 127 and drive shaft 129), both larger in diameter, on the guide wire;
5. Navigating the rotary cutting bar (grindstone 127) to a treatment site in a coronary artery;
6. Putting the drive control assembly on the guide wire; and
7. Operatively connecting the drive control assembly to the larger-diameter rotary cutting bar and drive shaft (grindstone 127 and drive shaft 129).

[0010] In view of the above-mentioned problem, the present invention has for its object to provide a medical instrument that, in the case of distending a narrowed vascular portion after

initial treatment, eliminates the need for pulling a rotating cutter off a guide wire and permits enlarging the diameter of the rotating cutter on the guide wire left remaining in the blood vessel.

[0011] Another object of the present invention is to provide a medical instrument that allows ease in enlarging the diameter of the rotating cutter on the guide wire after once pulling the rotating cutter out of a patient's body along the guide wire left remaining in the blood vessel.

[0012] Still another object of the present invention is to provide a medical instrument that permits quick and effective removal of an intravascular narrowing material by a rotating cutter.

DISCLOSURE OF THE INVENTION

[0013] To solve the above-described problem, the medical instrument of the present invention comprises:

a guide wire that is inserted at one end through a vascular portion narrowed by deposits and is extended at the other end out of a patient's body;

a rotating cutter that is rotatably and slidably guided over said guide wire and is driven to rotatingly cut away the deposits in said narrowed vascular portion;

a hollow drive shaft that is operatively connected to said rotating cutter and through which said guide wire is inserted;

a fixed sheath having inserted therein said drive shaft; and

a controller having a drive assembly for rotating said drive shaft;

wherein said rotating cutter is driven to perform intravascular treatment to establish patency of said narrowed vascular portion or to distend said vascular portion;

wherein in the case of further distending said narrowed vascular portion after cutting treatment, said rotating cutter can be pulled out of the patient's body along said guide wire, together with said drive shaft and said fixed sheath; and

said rotating cutter has a deformable member that expands radially on said guide wire after being pulled out of the patient's body.

[0014] According to the present invention, in the case of further distending the narrowed vascular portion, there is no need for rotating-cutter replacement work which involves pulling the guide wire out of the patient's body and completely taking the rotating cutter off the guide wire. This permits quick removal of intravascular deposits and distention of the narrowed vascular

portion.

[0015] In the present invention it is preferable that the deformable member of the rotating cutter be formed by a plurality of cutting blades arranged side by side on the rotating cutter circumferentially thereof.

[0016] With such a rotating cutter, it is possible to quickly remove deposits from the narrowed vascular site and hence distend the vessel simply by deforming the cutting blades radially of the rotating cutter to enlarge its diameter.

[0017] In the present invention the rotating cutter can be held in its radially expanded configuration by forming the cutting blades so that they are capable of plastic deformation in the radial direction of the rotating cutter.

[0018] In the present invention it is preferable that the cutting blades be deformable by a toggle mechanism radially of the rotating cutter to enlarge its diameter, or that the cutting blades be deformed by a wedge radially of the rotating cutter to enlarge its diameter.

[0019] In the present invention it is preferable that the rotating cutter be provided with a thermal contraction or expansion member for deforming the deformable member radially of the rotating cutter.

[0020] In the present invention it is preferable that the deformable member of the rotating cutter be formed of a shape-memory alloy or similar thermally deformable material.

[0021] Accordingly, the deformable member can be deformed radially of the rotating cutter simply by thermal deformation.

[0022] In the present invention it is preferable that a jig be provided for deforming the deformable member of the rotating cutter radially thereof and that the jig be disposed coaxially with or in proximity to the drive shaft.

[0023] With such a jig, the deformable member can easily be deformed radially of the rotating cutter to enlarge its diameter.

[0024] In the present invention it is preferable that the controller be provided with a mechanism for pushing out the rotating cutter from a distal end of the fixed sheath toward the treatment site forwardly thereof and a mechanism for pulling back the cutter, and that these mechanisms be actuated by a squeeze-type operating lever provided with an auto-return mechanism and a position-retaining mechanism.

[0025] With such an arrangement, the rotating cutter can easily be pushed out from the distal end of the fixed sheath toward the treatment site forwardly thereof and retracted therefrom.

[0026] In the present invention, it is preferable that a jig be provided for deforming the deformable member of the rotating cutter radially thereof, and that the jig be formed by a one-hand operated, squeeze-type lever mechanism which utilizes a force-multiplying mechanism by a lever or cam.

[0027] With such a jig, the deformable member of the rotating cutter can easily be deformed radially thereof to enlarge its diameter.

[0028] In the present invention it is preferable that the controller be provided with a vibrating mechanism for reciprocating the rotating cutter along the guide wire.

[0029] With such a vibrating mechanism, it is possible to impart combined cutting forces by rotary and reciprocating motions to the rotating cutter, thereby increasing or stabilizing the cutting force of the rotating cutter. Besides, the rotating cutter and the sheath can easily be inserted into a guiding catheter because of reduced friction between them.

[0030] In the present invention it is preferable that the controller has built therein a drive assembly for transmitting rotating force to the drive shaft, and that the drive assembly has a motor whose rotary shaft is hollow so that it permits the insertion therethrough of the drive shaft.

[0031] Such an arrangement eliminates the need for pulling off the drive shaft in its entirety from the guide wire but allows ease in pulling the drive shaft out of the patient's body along the guide wire left remaining within the body.

[0032] In the present invention it is preferable that the controller be provided with a drive shaft chucking mechanism and a soft-sheath attaching/detaching mechanism.

[0033] The chucking mechanism ensures transmission of motor driving force to the drive shaft. Moreover, the chucking mechanism allows ease in detaching the sheath from the controller in the case of performing interior maintenance of the controller.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] Fig. 1 is a perspective view explanatory of the usage pattern of a medical instrument according to a first embodiment of the present invention.

[0035] Fig. 2 shows, on an enlarged scale, a rotating cutter of the medical instrument of Fig. 1, Fig. 2(A) depicting a yet-to-be radially expanded configuration of the cutter and Fig. 2(B) its expanded configuration.

[0036] Fig. 3 is a diagram showing the structure of the front portion of a controller of the medical instrument depicted in Fig. 1 and explanatory of a method for enlarging the diameter of the rotating cutter.

[0037] Fig. 4 shows a rotating cutter diameter enlargement jig of a medical instrument according to a second embodiment of the present invention, Fig. 4(A) depicting the jig before enlargement of the diameter of the cutter and Fig. 4(B) after diameter enlargement.

[0038] Fig. 5 shows, in partially sectioned side elevation, the structure of a rotating cutter of a medical instrument according to a third embodiment of the present invention, Fig. 5(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 5(B) its expanded configuration.

[0039] Fig. 6 shows, in partially sectioned side elevation, the structure of a rotating cutter of a medical instrument according to a fourth embodiment of the present invention, Fig. 6(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 6(B) its expanded configuration.

[0040] Fig. 7 shows, in partially sectioned side elevation, the structure of a rotating cutter diameter enlargement jig of a medical instrument according to a fifth embodiment of the present invention, Fig. 7(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 7(B) its expanded configuration.

[0041] Fig. 8 is a perspective view showing, in its entirety, the enlargement jig depicted in Fig. 7.

[0042] Fig. 9 shows, in partially sectioned side elevation, the construction of a rotating cutter of a medical instrument according to a sixth embodiment of the present invention, Fig. 9(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 9(B) its expanded configuration.

[0043] Fig. 10 shows, in partially sectioned side elevation, the construction of a rotating cutter of a medical instrument according to a seventh embodiment of the present invention, Fig. 10(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 10(B) its expanded configuration.

[0044] Fig. 11 shows, in partially sectioned side elevation, the construction of a rotating cutter of a medical instrument according to an eighth embodiment of the present invention, Fig. 11(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 11(B) its expanded configuration.

[0045] Fig. 12 is a sectioned side elevational view showing the construction of a controller of a medical instrument according to a ninth embodiment of the present invention.

[0046] Fig. 13 is a sectioned side elevational view showing, on an enlarged scale, the construction of the principal part of the controller depicted in Fig. 12.

[0047] Fig. 14 is a sectioned side elevational view showing the controller of the medical instrument of Fig. 12, with a sheath connector taken away.

[0048] Fig. 15 is a schematic diagram for explaining how to scrape off deposits.

BEST MODE FOR CARRYING OUT THE INVENTION

[0049] To facilitate a better understanding of the present invention, the best mode for carrying out the invention will hereinafter be described with reference to the accompanying drawings.

[0050] Fig. 1 is a perspective view explanatory of the usage pattern of the medical instrument according to the first embodiment of the present invention.

[0051] Fig. 2 shows, on an enlarged scale, a rotating cutter of the medical instrument of Fig. 1, Fig. 2(A) depicting the yet-to-be radially expanded configuration of the cutter and Fig. 2(B) its expanded configuration.

[0052] Fig. 3 shows the front face portion of a controller of the medical instrument depicted in Fig. 1, for explaining how to enlarge the diameter of the rotating cutter.

[0053] At the lower left of Fig. 1 there is shown a narrowed vascular portion 10 that needs treatment. In the illustrated state a distal end portion of the medical instrument is inserted through the narrowed vascular portion 10.

[0054] The medical instrument is provided with a guide wire 1 that is inserted through the narrowed vascular portion 10, and a rotating cutter 2 that rotates about the guide wire 1 and slides on the wire 1 in the axial direction thereof. The rotating cutter 2 is affixed to a drive shaft 3. The drive shaft 3 is a hollow member formed of a soft and flexible material.

[0055] The drive shaft 3 is inserted in a fixed sheath 4 that is a flexible cover tube. The fixed sheath 4 is inserted in a guiding catheter 5.

[0056] Referring to Fig. 2, the construction of the rotating cutter 2 will be described in detail.

[0057] The rotating cutter 2 has a plurality of deformable elements 2a. The deformable elements 2a are formed by a plurality of cutting blades arranged circumferentially about a center axis of the cutter structure. The deformable elements 2a are joined together at their distal ends to form a shell-like forward head 2b, with their proximal ends joined together by a ring member 2c.

[0058] When the rotating cutter 2 is fixed at its distal or proximal end with respect to the guide wire 1 and pressed from the free end side toward the fixed end in the axial direction of the guide wire 1, central portions of the cutting blades forming the deformable elements 2a expand radially outwardly as shown in Fig. 2(B), enlarging the diameter of the deformable elements 2a .

[0059] As depicted in Fig. 1, the drive shaft 3 is connected to a controller 20. The controller 20 controls the drive shaft 3 for high-speed rotary motion and reciprocating motion (which will be descried in detail later on). In the front end face of the controller 20 there is formed an engaging concavity 21 for receiving the rear end portion of the rotating cutter 2 as shown in detail in Fig.

3. The concavity 21 has formed centrally thereof a hole through which the drive shaft 3 is slidably inserted.

[0060] As depicted in Fig. 3, the controller 20 further includes a movable jig 22 by which the rotating cutter 2 fitted in the engaging concavity 21 is pressed axially of the guide wire 1 into the radially expanded configuration, and an operating lever 23 for shifting the movable jig 22 in a directions in which to the rotating cutter 2 radially expands and contracts. The movable jig 22 is L-shaped in cross section, and has a front panel 22a perpendicular to the lengthwise direction of the guide wire and a base portion 22b that is extended from the front panel 22a toward the controller 20 and is pulled out of and retracted into the controller 20. In the front panel 22a there is formed a notch 22c. The operating lever 23 is fixed to an operating shaft 23a and rotates about the operating shaft 23a. The operating shaft 23a is affixed, in the controller 20, to one end of the base portion 22b of the movable jig 22. Turning the operating lever in one direction (counterclockwise), the operating shaft 23a also turns accordingly and the base portion 22b of the movable jig 22 is pulled out of the controller 20 to provide space between the front panel 22a and the front end face of the body of the controller 20. Turning the operating lever 23 in the reverse direction (clockwise), the operating shaft 23a also turns accordingly and the base portion 22b of the movable jig 22 is retracted into the controller 20, narrowing the space between the front panel 22a and the front end face of the controller 20.

[0061] Next, a description will be given of an operation for removal of deposits from the narrowed vascular portion 10 using the medical instrument.

[0062] The operation starts with inserting the guide wire 1 into the blood vessel until a distal end of the guide wire 1 passes through the narrowed vascular portion 10. At this time, the rotating cutter 2 remains unexpanded as depicted in Fig. 2(A). The next step is to navigate the rotating cutter 2 over the guide wire 1 to the narrowed vascular portion 10 while rotating the cutter at low speed. Upon arrival of the rotating cutter 2 at the narrowed vascular portion 10, the cutter 2 is driven at high speed. At this point, initial removal of the narrowed vascular portion 10 by the cutting blades of the rotating cutter 2 is carried out.

[0063] Upon this initial removal, in the case where the deposits of the narrowed vascular portion 10 have not completely been removed and hence needs further removal, the rotating cutter 2 is

once pulled out of the patient's body along the guide wire 1 together with the drive shaft 3 and the sheath 4, with the wire 1 held remaining in the blood vessel. The diameter of the rotating cutter 2 thus pulled out of the patient's body is enlarged as described below.

[0064] With reference to Fig. 3, a description will be given of the operation for enlarging the diameter of the rotating cutter 2.

[0065] In the first place, as shown in Fig. 3(A), the operating lever 23 is turned counterclockwise (from the broken-line to the solid-line position) to pull the base portion 22b of the movable jig 22 out of the controller, defining space between the front panel 22a of the movable jig and the front end face of the controller 20. Then the rotating cutter 2 brought out of the patient's body is put in the space, with the rear end portion of the cutter 2 received in the engaging concavity 21 (refer to Fig. 3(B)). At this time, the guide wire 1 is positioned at the notch 22c of the front panel 22a.

[0066] Thereafter, as shown in Fig. 3(c), turning the operating lever 23 clockwise (from the broken-line to the solid-line position), the base portion 22b of the movable jig 22 is retracted into the controller 20, and hence the front panel 22a moves toward the front end face of the controller 20 accordingly. As a result, the rotating cutter 2 held in the above-mentioned space is pressed between the front panel 22a of the movable jig 22 and the front end face of the controller 20. Thus, as shown on an enlarged scale in Fig. 2(B), the cutting blades of the rotating cutter 2 deform outwardly into the radially expanded configuration of the rotating cutter 2. Since the rotating cutter 2 is made of a plastic deformable material, it retains its shape after being deformed.

[0067] After radially expanded, the rotating cutter 2 is inserted again into the patient's body and navigated over the guide wire 1 to the narrowed vascular portion 10. Then the rotating cutter 2 is driven at high speed so that the enlarged cutting blades remove the deposits still remaining unremoved in the vessel.

[0068] According to this method, after initial removal of the deposits from the narrowed vessel 10, only the rotating cutter 2, the drive shaft 3 and the fixed sheath 4 are once brought out of the patient's body, with the guide wire 1 left remaining in the vessel, after which diameter of the rotating cutter 2 is enlarged. Following this, the diameter-enlarged rotating cutter 2 is inserted

again into the vessel and navigated over the guide wire 1 remaining in the vessel, and the enlarged rotating cutter 2 is driven to perform subsequent removal. Accordingly, this method avoids the need for cutter replacement work which calls for completely pulling out all of the guide wire 1, the rotating cutter 2, the drive shaft 3 and the fixed sheath 4 from the blood vessel and replacing the cutter with a larger-diameter one.

[0069] Fig. 4 illustrates a rotating cutter diameter enlargement jig of a medical instrument according to a second embodiment of the present invention, Fig. 4(A) showing a yet-to-be radially expanded configuration of the cutter and Fig. 4(B) its expanded configuration.

[0070] The diameter-enlarging jig of this example has a one-hand operated lever mechanism. The jig includes a pair of levers pivotally coupled by a pin P, a fixed base 7 fixedly mounted on an upper extremity of the one lever 6A, and a movable base 8 slidably mounted on the bottom of the fixed base 7.

[0071] The fixed base 7 is L-shaped in cross section, and has a bottom 7a fixed to the upper extremity of the lever 6A and an upright tab 7b standing upright from the bottom 7a. The movable base 8 is also L-shaped in cross section, and has a bottom 8a slidably mounted on the bottom 7a of the fixed base 7 and an upright tab 8b standing upright from the bottom 8a. The upright tab 7b of the fixed base 7 and the upright tab 8b of the movable base 8 are located opposite across the bottoms 7a and 8a of the both bases. With the lever released as shown in Fig. 4(A), the bottom 7a of the fixed base 7 and the bottom 8a of the movable base 8 stay apart. Incidentally, the bottom 8a of the movable base 8 is prevented, by a stop 8c at a distal end portion of the bottom 8a, from slipping off the bottom 7a of the fixed base 7. In the upright tab 7b of the fixed base 7 there is formed a notch for receiving a guide wire. The back of the upright tab 8b of the movable base 8 abuts against the upper extremity of the other operating lever 6B. In the inner wall of the upright tab 8b there are formed a recess 8d and a notch for receiving a fixed sheath.

[0072] In the case of using this jig to enlarge the cutter diameter, the first step is to hold the both levers 6A and 6B open apart as depicted in Fig. 4(A), defining space between the upright tab 7b of the fixed base 7 and the upright tab 8b of the movable base 8. This is followed by placing the rotating cutter 2 in the thus defined space. At this time, the guide wire is fitted in the notch of

the upright tab 7a of the fixed base 7 with a distal end of the rotating cutter 2 located by the side of the upright panel 7a. Then a proximal end portion of the rotating cutter 2 is fitted in the recess 8d in the upright tab 8b of the movable base 8, and the fixed sheath is fitted in the notch of the same upright tab.

[0073] Then, squeezing the lever with one hand to turn the both levers about the pin P, the bottom 8a of the movable base slides in the bottom 7a of the fixed base 7, and consequently the upright tab 8b of the movable base 8 moves toward the upright tab 7b of the fixed base 7. As a result, the rotating cutter 2 is pressed between the both upright tabs 7a and 8b, causing the cutting blades of the rotating cutter 2 to bend outwardly into its radially expanded configuration.

[0074] Fig. 5 illustrates, in partially sectioned side elevation, the construction of a rotating cutter of a medical instrument according to a third embodiment of the present invention, Fig. 5(A) showing a yet-to-be radially expanded configuration of the cutter and Fig. 5(B) its expanded configuration.

[0075] The rotating cutter 2 of this example has a hollow central axis portion 2f, and the deformable member 2a has a plurality of concavities 2d made in the cutting blades in the back surface thereof. The concavities 2d are each formed such that they extend circumferentially of the cutting blade on back surface thereof. The concavities 2d provide a toggle mechanism for the cutting blades. The proximal end portions of the cutting blades are fixed together by a clamping member 2e to the central axis portion 2f.

[0076] In the initial treatment of a narrowed vascular portion, the cutting blades are not radially expanded, keeping the diameter of the rotating cutter 2 at minimum as shown in Fig. 5(A). In the case of enlarging the diameter of the rotating cutter 2, as shown in Fig. 5(B), the clamping member 2e is loosened and the cutting blades are pushed from their proximal ends side toward the distal end of the rotating cutter 2 (toward the left-hand side in Fig. 5), compressing the rotating cutter 2. As a result, the cutting blades expand radially outwardly while locally bending under the action of the toggle mechanism, thus causing the rotating cutter 2 to assume its expanded configuration. After this, the proximal end portions of the expanding cutting blades are clamped by the clamping member 2e.

[0077] According to the method described above, it is possible to quickly expand the rotating cutter to a desired diameter by choosing the distance of movement of the clamping member 2e.

[0078] Fig. 6 illustrates, in a partially sectioned side elevation, the construction of a rotating cutter of a medical instrument according to a fourth embodiment of the present invention, Fig. 6(A) showing a yet-to-be radially expanded configuration of the rotating cutter and Fig. 6(B) its expanded configuration.

[0079] The rotating cutter 2 of this example has a hollow central axis portion 2f and a sleeve-like wedge 9 disposed between the central axis portion 2f and the cutting blades. In the outer periphery of a distal end portion of the wedge 9 there is formed a tapered protrusive wedge portion 9a. On the other hand, in the interior surface of a distal end of each cutting blade of the rotating cutter 2 there is formed a protrusive wedge engaging portion 2g.

[0080] In the case of enlarging the diameter of the rotating cutter 2 by radial expansion, the wedge 9 is moved distally along the central axis portion 2f from its initial position shown in Fig. 6(A). Then, as shown in Fig. 6(B), the wedge portion 9a at the distal end of the wedge 9 is pressed into between the central axis portion 2f and the wedge engaging portion 2g in the inside surface of the distal end of each cutting blade. As a result, the cutting blades bend outwardly, putting the rotating cutter 2 into the expanded configuration.

[0081] Fig. 7 illustrates, in a partially sectioned side elevation, the construction of a rotating cutter expanding jig of a medical instrument according to a fifth embodiment of the present invention, Fig. 7(A) showing a yet-to-be radially expanded configuration of the rotating cutter and Fig. 7(B) its expanded configuration.

[0082] Fig. 8 is a perspective view showing the expanding jig of Fig. 7 in its entirety.

[0083] The expanding jig of this example is formed by a pair of columnar press members 11. The one press member 11B is fitted in the other press member 11A. In the face of the press member 11A opposed to the press member 11B there is formed a concavity 11a of a predetermined configuration, whereas in the face of the press member 11B opposed to the press member 11A, too, there is formed a concavity 11b of a predetermined configuration. With the both press members engaged with each other, the concavities 11a and 11b form therebetween a

space defined by curved surfaces. As depicted in Fig. 8, the press members 11A and 11B have formed therein notches 11c and 11d extending axially thereof. Through these notches the drive shaft and the fixed sheath are fitted in the jig.

[0084] In the rotating cutter 2 of this example the deformable member 2a (cutting blades) has a solid front half portion and a rear half portion extending branched from the center of the rotating cutter 2 toward its rear end. In the exterior surface of the deformable member 2a there is formed centrally thereof a groove 2h extending circumferentially thereof. When radially expanded, the rotating cutter 2 is maximum in diameter in the vicinity of the groove 2h, allowing smooth deformation of the rear half portion extending rearwardly of the groove 2h.

[0085] In the case of using the expanding jig described above, the rotating cutter 2 is placed in the concavity defined by the both press members 11 held apart. At this time, the guide wire and others are received in the notches 11c and 11d of the press members 11. Then the press members 11 are interengaged and pressed to each other. As a result, the cutting blades of the rotating cutter 2 are pressed axially thereof and expand outward in conformity to the concavities 11a and 11b of the both press members 11. Thus the rotating cutter 2 radially expands.

[0086] Fig. 9 illustrates, in a partially sectioned side elevation, the construction of a rotating curter of a medical instrument according to a sixth embodiment of the present invention, Fig. 9(A) showing a yet-to-be radially expanded configuration of the cutter and Fig. 9(B) its expanded configuration.

[0087] The rotating cutter 2 of this example has a thermal expansion member 12 disposed between the central axis portion 2f and the deformable member 2a. The thermal expansion member 12 is annular in shape and thermally expands outward.

[0088] In the case of enlarging the diameter of the rotating cutter 2, the thermal expansion member 12 is heated from the outside, with the rotating cutter 2 pulled out of a blood vessel. As depicted in Fig. 9(B), when the thermal expansion member 12 expands, the deformable member 2a (the cutting blades) is pushed outward into the radially expanded configuration of the rotating cutter 2.

[0089] Fig. 10 illustrates, in a partially sectioned side elevation, the construction of a rotating

cutter of a medical instrument according to a seventh embodiment of the present invention, Fig. 10(A) showing a yet-to-be radially expanded configuration of the cutter and Fig. 10(B) its expanded configuration.

[0090] The rotating cutter 2 of this example has a thermal contraction member 14 disposed on one part of the proximal end portion of the deformable member 2a (cutting blades). The proximal end portion of the cutting blade 2a is tapered externally rearwardly as indicated by 2i. At the proximal end of the central axis portion 2f there is formed a flange 2j extending outwardly therefrom. The inside surface of the flange 2j (facing toward the rotating cutter) is tapered inwardly as indicated by 2k. Thus the tapered faces 2i and 2k of the cutting blade and the flange 2j define therebetween an annular groove 13. Accordingly, both sidewalls of the groove 13 are inclined inwardly in tapered form; hence, the area of the opening of the groove is larger than the area of its bottom.

[0091] The thermal contraction member 14 is annular in shape and contracts axially of the central axis portion. When the cutter is not radially expanded as shown in Fig. 10(A), the thermal contraction member 14 is located in the opening of the groove 13. To enlarge the diameter of the rotating cutter 2 by radial expansion, the thermal contraction member 14 is heated for thermal contraction. The thermal contraction member 14 contracts in the direction of the central axis portion 2f along the tapered sidewall faces 2j and 2k of the groove 13 and goes down into contact with the bottom of the groove 13. Then, the sidewalls of the groove 13 move away from each other in the axial direction, and the cutting blades 2a are urged against the flange 2k of the central axis portion 2f. Thus the cutting blades 2a bend outward into the radially expanded configuration of the rotating cutter to enlarge its diameter.

[0092] Fig. 11 illustrates, in a partially sectioned side elevation, the construction of a rotating cutter of a medical instrument according to an eighth embodiment of the present invention, Fig. 11(A) showing a yet-to-be radially expanded configuration of the cutter and Fig. 11(B) its expanded configuration.

[0093] The rotating cutter 2 of this example is composed of cutting blades 2a made of a shape-memory alloy. And the rotating cutter has a shape memory such that it takes on the Fig. 11(A) configuration in a normal environment and deforms into the Fig. 11(B) configuration in a high-

temperature environment. Furthermore, the central axis portion 2f has a large-diameter stepped portion 2n integral with its proximal end portion. When the rotating cutter 2 is yet-to-be radially expanded as shown in Fig. 11(A), the proximal ends of the cutting blades 2a are held on the stepped portion 2n. A ring member 2p for clamping the proximal ends of the cutting blades 2a is made of a contractile material.

[0094] In the case of enlarging the diameter of the rotating cutter 2, it is heated outside the patient's body. Then the cutting blades 2a expand into the Fig. 11(B) configuration as initially shape-memorized, and the proximal ends of the cutting blades 2a move forwardly away from the stepped portion 2n. Thereafter, when temperature drops and the cutting blades 2a are allowed to restore the configuration shown in Fig. 11(A), the proximal ends of the cutting blades 2a strike against the front edge 2q of the stepped portion 2n, with the result that the cutting blades 2a are held in the expanded configuration.

[0095] The rotating cutters of these embodiments are expandable only by thermal expansion, and hence they avoid the need for the jig for expansion, permitting simplification of the device.

[0096] Fig. 12 is a sectioned side elevational view illustrating the construction of a controller of a medical instrument according to a ninth embodiment of the present invention.

[0097] Fig. 13 is an enlarged sectioned side elevational view depicting the construction of the principal part of the controller of the medical instrument of Fig. 12.

[0098] Fig. 14 is a sectioned side elevational view showing the controller of the medical instrument of Fig. 12, with a sheath connector taken away.

[0099] As shown in Fig. 12, the controller 20 has a housing 30. The housing 30 has formed integrally therewith a grip 31 extending upwardly therefrom. The grip 31 has a grip lever 32 pivotally secured thereto through a pin 33. The grip lever 32 has a lever core bar 34, and the lever core bar 34 has attached thereto a lock lever 35 via the pin 33.

[00100] On the lower end portion of the lever core bar 34 is mounted a motor holder 36. In a mounting piece for mounting the motor holder 36 on the lever core bar 34 there is formed a guide slit 37. Fitted in the guide slit 37 is a guide pin 38 projecting from the lower end portion of

the lever core bar 34. The motor holder 36 has housed therein a motor 39.

[00101] A rotary shaft of the motor 39 has fitted thereon an eccentric cam 40. In the periphery of the eccentric cam 40 there is fitted a bearing holder 41 through bearings 42. The bearing holder 41 has a depending pin 41a integrally extending downward therefrom. The housing 30 has built therein a cylindrical slider 43. The slider 43 is operatively connected to the depending pin 41a of the bearing holder 41 in a manner to reciprocate axially thereof.

[00102] As depicted in detail in Fig. 13, an armature core 44 is disposed on the inner surface of the slider 43, and an armature coil 45 is disposed on the inside of the armature core 44. Disposed inside the armature coil 45 is a rotor magnet 46. The armature core 44, the armature coil 45 and the rotor magnet 46 constitute a drive-shaft driving motor assembly 47. The motor assembly 47 contains a Hall sensor 48.

[00103] In the rotor magnet 46 there is disposed a chuck pawl connecting member 50 in a manner to be movable in its axial direction. To the front extremity of the chuck pawl connecting member 50 is threadably attached a chuck pawl 51. The chuck pawl connecting member 50 and the chuck pawl 51 have inserted therethrough the drive shaft 3. The chuck pawl 51 is biased by a spring 52 through the chuck pawl connecting member 50 in the axial direction of the drive shaft 3. At the rear end of the chuck pawl connecting member 50 a cylinder knob 53 for chucking release is mounted through a cylinder holder 54 in a manner to be movable in its axial direction. The cylinder knob 53 is biased by a spring 55 in a direction opposite to the chuck pawl connecting member 50.

[00104] To the front end of the housing 30 a sheath connector 60 is detachably attached about the drive shaft 3. The soft fixed sheath 4 is fitted on the sheath connector 60 to provide communication between the sheath connector 60 and the fixed sheath 4. The sheath connector 60 has pressed therein a mechanical seal 61, and the mechanical seal 61 makes sliding contact with the drive shaft 3. A saline supply tube 62 communicates with the sheath connector 60.

[00105] Next, a description will be given of the operation of the controller 20.

[00106] After the rotating cutter 2 has been navigated over the guide wire 1 to the narrowed vascular portion 10 as shown in Fig. 1, when the drive-shaft driving motor assembly

47 is brought into operation, the drive shaft 3, the chuck pawl 51 chucking the drive shaft 3 and the chuck pawl connecting member 50 coupled to the chuck pawl 51 rotate as a unit with the rotor magnet 46. By this, the rotating cutter at the distal end of the drive shaft 3 rotates to remove deposits from the narrowed vascular portion 10.

[00107] Putting the motor 39 into operation during rotation of the rotating cutter 2, the eccentric cam 40 rotates and the bearing holder 41 fitted in the eccentric cam 40 also rotates eccentrically. Then the slider 43 connected to the depending pin 41a of the bearing holder 41 reciprocates axially thereof. As a result, the drive shaft 3 reciprocates axially thereof through the drive-shaft driving motor assembly 47 provided unitary with the slider 43 and the chuck pawl 51. Accordingly, the rotating cutter 2 at the extreme end of the drive shaft 3 is imparted a rotary motion as well as a reciprocating motion along the guide wire 1, ensuring increasing or stabilizing the cutting force of the rotating cutter 2 for removing deposits in the narrowed vascular portion 10.

[00108] In the case of treating the narrowed vascular portion 10 for further distending it after the initial removal by the rotating cutter 2, the rotating cutter 2 and the drive shaft 3 are once pulled out along the guide wire 1 from the patient's body. At this time, it is necessary to release the drive shaft 3 from chucking by the chuck pawl 51. In this case, by pushing the cylinder knob 53 for chucking release against the spring 55, the chuck pawl connecting member 50 moves forward against the spring 52. Then the chuck pawl 51 opens to release the drive shaft 3, and hence the drive shaft 3 can be easily pulled out along the guide wire 1 from the patient's body.

[00109] According to the method described above, since the mechanical drive assembly of the controller 20 is configured to impart a reciprocating motion by the drive-shaft driving motor assembly 47 and a rotary motion by the motor 39 to the rotating cutter 2, the cutting force for removing deposits in the narrowed vascular portion 10 can be increased by the combination of reciprocating and rotary motions. This ensures increasing or stabilizing the cutting force of the rotating cutter 2 for removing deposits in the narrowed vascular portion 10. Additionally, the rotating cutter 2 and the sheath 4 can be inserted into the guiding catheter 5 with less friction.

INDUSTRIAL APPLICABILITY

[00110] As is evident from the above description, according to the present invention, in the case of enlarging the diameter of a rotating cutter by its radial expansion after initial removal of a narrowed vascular portion, the rotating cutter is once pulled out along a guide wire from a patient's body, together with a drive shaft and a fixed sheath, with the guide wire left remaining in the patient's body, and the rotating cutter thus drawn out of the body can be expanded radially on the guide wire. Accordingly, in the case of distending the narrowed vascular portion by further cutting, there is no need for replacement of the rotating cutter after completely removing it with the controller from the guide wire. This permits quick distention of the narrowed vascular portion by cutting deposits therein.

[00111] Moreover, since the deformable member of the rotating cutter is formed in one-piece structure of multiple cutting blades arranged side by side circumferentially of the rotating cutter such that they are all deformable radially of the rotating cutter, distention of the narrowed vascular portion by cutting deposits therein can be promptly achieved simply by deforming the cutting blades radially outwardly.